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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,886	10/24/2003	George Goicoechea	BSI-210US7	1904

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EXAMINER	
HO, UYEN T	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/692,886	GOICOECHEA ET AL.	
	Examiner	Art Unit	
	(Jackie) Tan-Uyen T. Ho	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-84 and 93-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-84 and 93-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Information Disclosure Statement

2. All of the information disclosure statements filed 8/9/06 fail to comply with 37 CFR 1.98(a)(1), which requires the following: (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

3. The information disclosure statement (IDS) submitted on 7/3/06 is being considered by the examiner.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 08/463,987, 08/317,763 and 08/312,881 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed applications fail to provide adequate support in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 54-56, 60, 62-66, 71-84, 97, 101, 125, 126. Accordingly, claims 54-56, 60, 63-66, 71-84, 97, 101, 125, 126 are not entitled to the benefit of the prior applications.

Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the subject matter as claimed in claims 54-56, 60, 63-66, 71-84, 97, 101, 125 and 126 not disclosed in the prior-filed application: 08/463987 and 08/317,763.

Later-filed application was not filed by the same inventors in the prior-filed applications, 08/463,987; 08/317,763; EP94400284; and EP94401306.9.

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/312,881, filed on 9/27/04.

6. Because Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) and 120 as indicated above, the Examiner identified the priority date for claims 54-128 as follow:

The following claims have the prior benefit date of application 08/312,881 filed 9/27/94: claims 57-59, 61, 67-70, 84, 93-96, 98, 100, 102-116, 118-124 and 127

All other claims including: 54-56, 60, 62-66, 71-83, 97, 101, 125, 126 and 128 have the benefit date as the filing date of this application which is 10/24/03

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Specification does not provide proper antecedent basis for:

- A plurality of radially expandable prosthetic (recited in claims 54-56).
- Markers under imaging to indicate at least one of axial and rotational position of the stent graft (recited in claim 57-59).
- A rotational indicator (recited in claim 59)
- A plurality of alternative branch prosthetic modules having different prosthetic characteristic (recited in claims 54-56, 60 ...etc.)

- The composite radiographic image of the radiographic indicia varies with the rotational orientation of the module (recited in claim 63).
- A plurality of separate spaced apart wires (recited in claims 71, 75)
- Separate spaced apart wire comprises two opposing ends being joined together on the outside surface of a primary graft body (recited in claims 72, 76).
- The reinforcement wires has different amplitude than the next adjacent wire (recited in claims 79, 80).
- The primary graft body is crimped along its length (recited in claim 82).
- The supplemental graft is crimped along its length (recited in claim 83).
- A multi-layer graft body (recited in claim 97)
- The wire structure is interwoven with the surface of the respective graft body (recited in claims 101, 126)
- Frusto-conical (recited in claim 103)
- Skirt portion (recited in claim 105)
- Sinusoidal shape (recited in claim 111)
- The divergent flow lumens (recited in claim 115)
- A plurality of separate, spaced apart, malleable wire (recited in claim 122)
- The wavelength of the wires is substantially constant along a length of the graft body

8. The amendments filed 9/3/2004, 2/4/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Amendment filed 9/3/04

- A plurality of separate spaced apart wires (recited in claims 71, 75);
- The ends of each of the separate wires joined together on the outside surface of the supplemental graft body (recited in claim 76)
- Material of said primary graft body is crimped along its length (recited in claim 82)
- Material of said supplemental graft body is crimped along its length (recited in claim 83).

Amendment filed 2/4/05

- The wire structure is interwoven with the surface of the respective graft body (recited in claims 101, 126)

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 71-81 and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification does not support the subject matters:

- "...said primary graft body is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires" as recited in claim 71
- "...each of said separate spaced apart wires comprises two opposing end...being joined together on the outside surface of said primary graft body" as recited in claim 72.
- "...said supplemental graft body is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires" as recited in claim 75
- "...each of said separate spaced apart wires comprises two opposing end...being joined together on the outside surface of said primary graft body" as recited in claim 76.
- "...a tubular graft body which is circumferentially reinforced along its length by a plurality of separate spaced apart... wires" as recited in claim 75

Note: In the Remarks filed 12/23/05, applicants argued that page 22, 23, 26, 29 of the specification described the subject matters of claims 71-81 and 123 as listed above. Examiner disagrees. Page 22, specification discloses the bifurcated stent in fig. 1a having four separated parts that are connected together. Each part can be made from a separate wire but it is clearly show in figures 1 and in the specification that the wires are connected together to form a support frame supporting the primary or

supplemental graft and the wires. The specification does not support four separated spaced apart wires circumferentially reinforced along the length of supplemental or primary graft. Fig. 1a clearly show reinforced stent being made from connected wires. Regarding the ends of each wire being joined together as claimed in claims 72 and 76, applicant argues that Fig. 4A (col. 7, lines 58-60; col. 10, lines 18-22) and col. 5, lines 5-6 of the specification describes the ends of each wire being joined together as claimed in claims 72 and 76. Examiner disagrees. First, there is no col. 5, 7 or 10 in the specification. Secondly, the specification discloses securing means 99 connecting the hoops of the wires together. Nowhere in the specification describes the ends of a wire being joined together and/or joined by the securing means 99 or by other means.

11. Claims 82-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 82 and 83 recited "said primary graft body is crimped along its length" and said supplemental graft body is crimped along its length," these subject matter were not described in the specification in such a way as to reasonably convey to one skill in the art that inventors, at the time the application was filed, had possession of the claimed. The specification does not disclose why and how to crimp the material of the primary graft or supplemental graft body along its length.

12. Claim 97 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not support a multi-layered graft body and the wire structure is sandwiched between layers of the multi-layered graft body.

13. Claims 101 and 126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose the stent interwoven with the graft. The specification discloses the stent being attached to the graft either inside or outside of the graft by stitching with filament. Since the term "interwoven" encompasses a broad range of structures and the original specification only support stitching structure, thus the specification does support other structures as the term "interwoven" encompasses.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 57-58, 61, 62, 64-70, 84, 93-96, 98-100, 102, 104-121 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin (5,575,817).

Regarding claims 57-58, Martin discloses a prosthetic apparatus comprising a radially expandable tubular frame (7); a liner (3); markers (12) adapted to indicate at least an axial position of the stent-graft in a compressed mode or an expanded mode, Although, Martin does not explicitly describe an attached mechanism, the prosthetic apparatus of Martin inherently include an attached mechanism for attached the liner (3) to the tubular frame (7).

Regarding claims 61-62, Martin discloses a method of deploying the prosthetic in a body lumen (col. 3, line 45 to col. 4, line 32) comprising the steps as claimed. The portions including wire (12) have different radiopacity than portions without wire such that to facilitating proper alignment of modules 5 and 2.

Regarding claims 64-66, Martin discloses a first introducer (Fig. 3), a second introducer (a 5 French catheter, col. 3, line 65 to col. 4, line 27) and a male engaging portion (upper end of section 2) and female portion (lower limb 5, see fig. 1, 4; col. 3, lines 23-39).

Regarding claims 67-70, 84, 93-96, 98-100, 102, 104-121, Martin discloses a bifurcated stent-graft comprising a primary for first body graft (1) having a pair of connector legs (4, 5), a supplemental or second graft having an end dockable in an end or skirt of the first body graft (col. 3, the skirt being an end leg 5) and the graft being formed of a thin PTFE material (col. 3, lines 4-5), wherein the support/reinforced wire

frame disposed inside and outside the graft (fig. 1, col. 3, lines 1-39), reinforced members (9, 15) including a plurality of apices extending beyond at least a portion of the tubular graft end and the wire forming reinforced members having closed sinusoidal shape (fig. 1).

16. Claims 71-83 are rejected under 35 U.S.C. 102(e) as being anticipated by White et al. (6,613,073). White et al. disclose a graft for treatment aneurysms comprising a primary graft body and a supplemental graft body with all the components as claimed (Claims 71-83 are copied from claims 1-19 of the patent).

17. Claims 122-128 are rejected under 35 U.S.C. 102(e) as being anticipated by Piplani et al. (5,489,295). Piplani et al. disclose stent-graft comprising a radially expandable tubular frame having a plurality of separate, spaced apart malleable wires in zigzag shape (126, 127) having crests or apices projecting beyond at least part of the end of a flexible liner (112) supported by the frame, an attachment mechanism (144) which holds the liner on the frame; and a plurality of markers (121) attached to the liner which disposed on the frame to indicate axial and rotational position of the stent-graft. Note: the claim languages do not exclude the markers indirectly disposed on the frame.

18. Claims 57-59, 67, 68, 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Chuter (5,387,235). Chuter discloses a tubular frame (fig. 2, fig. 21), a flexible liner (fig. 22), an attachment mechanism holding the liner on the frame (fig. 6), markers adapted to indicate rotational position of the stent-graft (col. 17, lines 41-52, col. 25, lines 51-52) as the markers are used to reveal twisting of contralateral limb (210), it is adapted to reveal the rotational position of the stent-graft.

Regarding claim 67, Chuter discloses a bifurcate base structure (206) having a pair of connector legs (210, 213), grafts (246 and 247) are adapted to be anchored within one of the flow lumens of the legs since the grafts is contractible and expandable. Note: the claim limitations do not positively cite a graft being anchored within one of the flow, the claims limitation only claim the graft is adapted to.

Regarding claims 68-69, Chuter discloses a first graft having a proximal portion (206), first and second distal portions (210, 213), a second graft (246, 247) adapted to be inserted into a lumen of the first graft (206) wherein the graft are formed of a thin biocompatible material (col. 9, lines 11-25).

Regarding claims 70 and 84, Chuter discloses a primary graft (206), a supplemental graft having an end dockable to a portion of the primary graft (fig. 41), wherein the graft are formed of a thin biocompatible material (col. 9, lines 11-25). With a broadest reasonable interpretation, "dockable" encompasses join. Chuter clearly shows in figure 41 that member 247 join with member 206 by suture.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 54-56, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '817 in view of Sparks (3,357,432). Martin discloses all the limitations of the

claims except fails to teach a plurality of expandable prosthetic modules provide different selectable assembled prosthetic characteristic. It is well known in the art that size and shape of vascular prosthetic modules depending on the size and shape of the body portion to be grafted. It also well known in the surgical area that if not custom made, produces prosthetic devices in different size and shape in order to provide a better fit for example, Sparks discloses graft formed to have a plurality of different shape and size that can be selected (col. 3, lines 27-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plurality of different size and shape prosthetic modules for Martin's bifurcate graft apparatus in order to better accommodate the vessel to be grafted during a surgical procedure.

21. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '817 in view of Sparks (3,357,432) further in view of Marin et al. (5,507,769). Martin '817 discloses all the limitations of the claims except for a presence of fluoroscopy as claimed. Marin et al. discloses a rotational alignment being determined by fluoroscopy as claimed (Col. 10, lines 5-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a rotational alignment based on the fluoroscopy of the markers on the graft in order to enhance the placement of the graft.

22. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (5,575,817) in view of Lazarus et al. (5,275,622). Martin discloses a prosthetic apparatus comprising a radially expandable tubular frame (7); a liner (3); markers (12)

adapted to indicate at least an axial position of the stent-graft in a compressed mode or an expanded mode. Although, Martin does not disclose markers comprising a rotational indicator, Lazarus et al. disclose markers being a rotational indicator (col. 13, lines 18-36). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a rotational indicator comprising markers as claimed in view of Lazarus in order to provide a rotational indicator so that to enhance the placement of the graft.

23. Claims 97 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '817 in view of Hachtman et al. (5,645,559). Martin discloses all the limitations of the claims except for a presence of multi-layered graft and a wire structure/stent being sandwiched between layers. Hachtman et al. disclose a stent being sandwiched between layers to resist tissue growth through the stent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ multi layer graft into Martin's stent-graft in order to resist tissue growth through the stent/wire. Doing so would result the claimed invention of claim 101 as "interwoven" encompasses "blend together."

24. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '817 in view of Martin (5,653,743). Martin '817 discloses all the limitations of the claim except for a presence of a second graft body being frusto-conical in shape. It is well known in the art to have a vessel portion that are tapered for example Martin '743 disclose a graft body having a frusto-conical in shape which is tapered over the length of the graft in order to fit in a tapered vessel portion. Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the second graft body of Martin '817 reference to have a frusto-conical shape as claimed in order to accommodate a tapered vessel portion.

25. Claims 54, 55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuter (5,387,235) in view of Sparks (3,357,432). Chuter discloses all the limitations of the claims except fail to teach a plurality of expandable prosthetic modules provide different selectable assembled prosthetic characteristic. It is well known in the art that size and shape of vascular prosthetic modules depending on the size and shape of the body portion to be grafted. It also well known in the surgical area that if not custom made, produces prosthetic devices in different size and shape in order to provide a better fit for example, Sparks discloses graft formed to have a plurality of different shape and size that can be selected (col. 3, lines 27-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plurality of different size and shape prosthetic modules for Chuter's bifurcate graft apparatus in order to better accommodate the vessel to be grafted during a surgical procedure. Chuter discloses the graft (206) fittingly engaging the limb (246, 247) by suture (209).

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on Multiflex Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

(Jackie) Tan-Uyen T Ho
Primary Examiner
Art Unit 3731

January 2, 2007

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